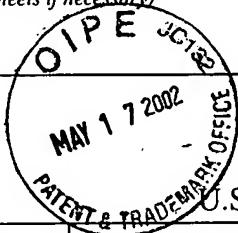


Form PTO-1449

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)



Docket Number 368292000200	Application Number 10/025,514
Applicant	Philip J. BARR et al.
Filing Date December 18, 2001	Group Art Unit 1653
Mailing Date May <u>10</u> , 2002	

**COPY**

## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	06/11/1985	4,522,811	Eppstein et al.			
	2.	03/22/1988	4,732,973	Barr et al.			
	3.	05/24/1988	4,746,648	Wagnon et al.			
	4.	06/21/1988	4,752,576	Brake et al.			
	5.	07/26/1988	4,760,130	Thompson et al.			
	6.	07/04/1989	4,845,076	Heinzel et al.			
	7.	09/26/1989	4,870,008	Brake			
	8.	10/10/1989	4,873,316	Meade et al.			
	9.	03/03/1992	5,093,316	Lezdey et al.			
	10.	03/01/1994	5,290,762	Lezdey et al.			
	11.	07/12/1994	5,328,470	Nabel et al.			
	12.	11/07/1995	5,464,822	Christophers et al.			
	13.	01/21/1997	5,595,885	Stetler-Stevenson et al.			
	14.	05/27/1997	5,633,227	Muller et al.			
	15.	07/01/1997	5,643,752	Hawkins et al.			
	16.	07/14/1998	5,780,440	Lezdey et al.			
	17.	12/15/1998	5,849,691	Majer et al.			
	18.	12/22/1998	5,851,983	Sugiyama et al.			
	19.	02/16/1999	5,871,956	Bandyopadhyay et al.			
	20.	05/04/1999	5,900,400	Thompson et al.			
	21.	06/22/1999	5,914,392	Hawkins et al.			
	22.	11/16/1999	5,985,309	Edwards et al.			
	23.	01/25/2000	6,017,880	Eisenberg et al.			
	24.	05/30/2000	6,068,994	Barr			
	25.	09/26/2000	6,124,257	Lezdey et al.			
	26.	10/17/2000	6,131,566	Ashurst et al.			

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449		Docket Number 368292000200	Application Number 10/025,514
INFORMATION DISCLOSURE CITATION IN AN APPLICATION		Applicant	Philip J. BARR et al.
(Use several sheets if necessary)		Filing Date December 18, 2001	Group Art Unit 1653
		Mailing Date May 10, 2002	

COPY

	27.	10/24/2000	6,136,295	Edwards et al.			
	28.	11/07/2000	6,143,277	Ashurst et al.			
	29.	02/13/2001	RE37,053 E	Hanes et al.			
	30.	07/03/2001	6,253,762 B1	Britto			
	31.	07/03/2001	6,254,854 B1	Edwards et al.			
	32.	09/18/2001	6,291,662 B1	Bandyopadhyay et al.			

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES	NO
	33.	03/09/1983	EP 0 073 657 A1, B1	Europe				
	34.	04/10/1986	WO 86/02100 A1	WIPO				
	35.	06/19/1986	WO 86/03519 A1	WIPO				
	36.	04/20/1988	EP 0 264 166 A1	Europe				
	37.	12/27/1990	EP 0 404 750 B1	Europe				
	38.	04/19/1995	EP 0 648 838 A1	Europe				

## OTHER DOCUMENTS

(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	39.	Agarwal, N. S. and Rich, D. H. (1986). "Inhibition of Cathepsin D by Substrate Analogues Containing Statine and by Analogues of Pepstatin," <i>J. Med. Chem.</i> 29:2519-2524.
	40.	Ausubel, F. M. et al. (2001). <i>Current Protocols in Molecular Biology</i> . John Wiley & Sons, Inc. 11 pages total (Table of Contents for Volumes 1-4 only).
	41.	Aviles, F. X. (1993). <i>Innovations in Proteases and Their Inhibitors</i> . W. DeGruyter, Berlin, N.Y. total pages 5. (Table of Contents).
	42.	Baldwin, E. T. et al. (July 1993). "Crystal Structures of Native and Inhibited Forms of Human Cathepsin D: Implications for Lysosomal Targeting and Drug Design," <i>Proc. Natl. Acad. Sci.</i> 90:6796-6800.
	43.	Banerji, J. et al. (July 1983). "A Lymphocyte-Specific Cellular Enhancer is Located Downstream of the Joining Region in Immunoglobulin Heavy Chain Genes," <i>Cell</i> 33:729-740.

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449  INFORMATION DISCLOSURE CITATION IN AN APPLICATION  (Use several sheets if necessary)		Docket Number 368292000200	Application Number 10/025,514
		Applicant	Philip J. BARR et al.
		Filing Date December 18, 2001	Group Art Unit 1653
		Mailing Date May <u>10</u> , 2002	

**COPY**

44.	Barnes, P. J. (February 2000). "Mechanisms in COPD: Differences From Asthma," <i>Chest</i> 117(2):10S-14S.
45.	Barnes, P. J. (July 2000). "Chronic Obstructive Pulmonary Disease," <i>Medical Progress</i> 343(4):269-280.
46.	Barrett, A. J. et al. (1986). "Cysteine Proteinase Inhibitors of the Cystatin Superfamily," Chapter 18 <i>In Proteinase Inhibitors</i> . A. J. Barrett and G. Salvesen eds., Elsevier Science Publishers, pp. 515-568.
47.	Beaucage, S. L. and Caruthers, M. H. (1981). "Deoxynucleoside Phosphoramidites-A New Class of Key Intermediates for Deoxypolynucleotide Synthesis," <i>Tetrahedron Letters</i> 22(20):1859-1862.
48.	Bingle, L. and Tetley, T.D. (1996). "Secretory Leukoprotease Inhibitor: Partnering $\alpha_1$ -Proteinase Inhibitor to Combat Pulmonary Inflammation," <i>Science Matters</i> 51:1273-1274.
49.	Bode, W. and Huber, R. (1992). "Natural Protein Proteinase Inhibitors and Their Interaction with Proteinases," <i>Eur. J. Biochem.</i> 204:433-451.
50.	Bode, W. and Huber, R. (1994). "Proteinase-Protein Inhibitor Interactions," <i>Fibrinolysis</i> 8 (Suppl. 1):161-171.
51.	Bode, W. and Huber, R. (2000). "Structural Basis of The Endoproteinase-Protein Inhibitor Interaction," <i>Biochimica et Biophysica Acta</i> 1477:241-252.
52.	Boone, T. C. et al. (April 1990). "cDNA Cloning and Expression of a Metalloproteinase Inhibitor Related to Tissue Inhibitor of Metalloproteinases," <i>Proc. Natl. Acad. Sci.</i> 87:2800-2804.
53.	Byrne, G. W. and Ruddle, F. H. (July 1989). "Multiplex Gene Regulation: A Two-Tiered Approach to Transgene Regulation in Transgenic Mice," <i>Proc. Natl. Acad. Sci.</i> 86:5473-5477.
54.	Calame, K. and Eaton, S. (1988). "Transcriptional Controlling Elements in the Immunoglobulin and T Cell Receptor Loci," <i>Adv. in Immunol.</i> 43:235-275.
55.	Camper, S. A. and Tilghman, S. M. (1989). "Postnatal Repression of the $\alpha$ -Fetoprotein Gene is Enhancer Independent," <i>Genes &amp; Dev.</i> 3:537-546.
56.	Carrell, R.W. et al. (July 1982). "Structure and Variation of Human $\alpha_1$ -Antitrypsin," <i>Nature</i> 298:329-334.
57.	Cawston, T. E. (1995). "Proteinases and Inhibitors," <i>British Medical Bulletin</i> 51(2):385-401.
58.	Chen, S. H et al. (April 1994). "Gene Therapy for Brain Tumors: Regression of Experimental Gliomas by Adenovirus-Mediated Gene Transfer <i>In Vivo</i> ," <i>Proc. Natl. Acad. Sci.</i> 91:3054-3057.
59.	Coligan, J. E. et al. (1991). <i>Current Protocols in Immunology</i> . John Wiley & Sons, Inc. 10 pages total. (Table of Contents of Volumes 1-3 only).
60.	Collier, I. E. et al. (May 1988). "H-ras Oncogene-transformed Human Bronchial Epithelial Cells (TBE-1) Secrete a Single Metalloprotease Capable of Degrading Basement Membrane Collagen," <i>The J. of Biol. Chem.</i> 263(14):6579-6587.

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449		Docket Number 368292000200	Application Number 10/025,514
INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i>		Applicant Philip J. BARR et al.	
		Filing Date December 18, 2001	Group Art Unit 1653
		Mailing Date May <u>10</u> , 2002	

COPY

61.	Docherty, A. J. P. et al. (November 1985). "Sequence of Human Tissue Inhibitor of Metalloproteinases and its Identity to Erythroid-Potentiating Activity," <i>Nature</i> 318:66-69.
62.	Eckman, E.A. et al. (August 1999). "In Vitro Transport of Active $\alpha_1$ -Antitrypsin to the Apical Surface of Epithelia by Targeting the Polymeric Immunoglobulin Receptor," <i>Am. J. Respir. Cell Mol. Biol.</i> 21:246-252.
63.	Edlund, T. et al. (November 1985). "Cell-Specific Expression of the Rat Insulin Gene: Evidence for Role of Two Distinct 5' Flanking Elements," <i>Science</i> 230:912-916.
64.	Edwards, D.A. et al. (June 1997). "Large Porous Particles for Pulmonary Drug Delivery," <i>Science</i> 276:1868-1871.
65.	Ferkol, T. et al. (March 2000). "Transport of Bifunctional Proteins Across Respiratory Epithelial Cells Via the Polymeric Immunoglobulin Receptor," <i>Am. J. Respir. Crit. Care Med.</i> 161(3):944-951.
66.	Fiers, W. et al. (May 1978). "Complete Nucleotide Sequence of SV40 DNA," <i>Nature</i> 273:113-120.
67.	Francis, S. E. et al. (1994). "Molecular Characterization and Inhibition of a <i>Plasmodium Falciparum</i> Aspartic Hemoglobinase," <i>The EMBO J.</i> 13(2):306-317.
68.	Freshney, R. I., ed. (1987). <u>Animal Cell Culture: A Practical Approach</u> . IRL Press at Oxford University Press. pages ix-xiv. (Table of Contents).
69.	Gait, M. J. ed., (1984). <u>Oligonucleotide Synthesis: A Practical Approach</u> . IRL Press at Oxford University Press. pp.vii-xii., (Table of Contents).
70.	Gasson, J. C. et al. (June 1985). "Molecular Characterization and Expression of the Gene Encoding Human Erythroid-Potentiating Activity," <i>Nature</i> 315:768-771.
71.	Goeddel, D.V. (1990). "Gene Expression Technology," In <u>Methods in Enzymology</u> , Academic Press, Inc. San Diego 185:v-ix. (Table of Contents).
72.	Gottesman, S. (1990). "Minimizing Proteolysis in <i>Escherichia Coli</i> : Genetic Solutions," <u>Methods in Enzymology</u> . J. N. Abelson and M. I. Simon, eds., Academic Press, Inc. 185:118-129.
73.	Guyene, T. T. et al. (December 1976). "Inhibition of Human Plasma Renin Activity by Pepstatin," <i>The J. of Clin. Endocrinol. and Metab.</i> 43(6):1301-1306.
74.	Heinzel, R. et al. (1986). "Molecular Cloning and Expression of cDNA for Human Antileukoprotease from Cervix Uterus," <i>Eur. J. Biochem.</i> 160: 61-67.
75.	Hercz, A. (April 1985). "Proteolytic Cleavages In $\alpha_1$ -Antitrypsin and Microheterogeneity," <i>Biochem. and Biophys. Res. Comm.</i> 128(1):199-203.
76.	Huang, W. et al. (1996). "Folding and Characterization of the Amino-Terminal Domain of Human Tissue Inhibitor of Metalloproteinases-1 (TIMP-1) Expressed at High Yield in <i>E. Coli</i> ," <i>FEBS Lett.</i> 384:155-161.
77.	Huff, J. R. (August 1991). "HIV Protease: A Novel Chemotherapeutic Target for AIDS," <i>J. of Med. Chem.</i> 34(8):2305-2314.

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449  INFORMATION DISCLOSURE CITATION IN AN APPLICATION  <i>(Use several sheets if necessary)</i>		Docket Number 368292000200	Application Number 10/025,514
		Applicant	Philip J. BARR et al.
		Filing Date December 18, 2001	Group Art Unit 1653
		Mailing Date May 10, 2002	<b>COPY</b>

78.	Jupp, R. A. (July 1990). "The Selectivity of Statine-Based Inhibitors Against Various Human Aspartic Proteinases," <i>Biochem. J.</i> 265:871-878.
79.	Lin, T. Y. and Williams, H. R. (December 1979). "Inhibition of Cathepsin D by Synthetic Oligopeptides," <i>J. Biol. Chem.</i> 254(23):11875-11883.
80.	Kessel, M. and Gruss, P. (July 1990). "Murine Development Control Genes," <i>Science</i> 249:374-379.
81.	Kubo, T. et al. (December 1988). "Location of a Region of the Muscarinic Acetylcholine Receptor Involved in Selective Effector Coupling," <i>FEBS Lett.</i> 241(1,2):119-125.
82.	Kurachi, K. et al. (November 1981). "Cloning and Sequence of cDNA Coding for $\alpha_1$ -Antitrypsin," <i>Proc. Natl. Acad. Sci.</i> 78(11):6826-6830.
83.	Kurjan, J. and Herskowitz, I. (October 1982). "Structure of a Yeast Pheromone Gene (Mf $\alpha$ ): A Putative $\alpha$ -Factor Precursor Contains Four Tandem Copies of Mature $\alpha$ -Factor," <i>Cell</i> 30:933-943.
84.	Matteucci, M. D. and Caruthers, M. H. (1981). "Synthesis of Deoxyoligonucleotides on a Polymer Support," <i>J. Am. Chem. Soc.</i> 103(11):3185-3191.
85.	McElvaney, N. G. et al. (October 1992). "Modulation of Airway Inflammation in Cystic Fibrosis: In Vivo Suppression of Interleukin-8 Levels on the Respiratory Epithelial Surface by Aerosolization of Recombinant Secretory Leukoprotease Inhibitor," <i>The J. of Clin. Inves.</i> 90:1296-1301.
86.	Merrifield, R. B. (July 1963). "Solid Phase Peptide Synthesis. I. The Synthesis of a Tetrapeptide," <i>J. Amer. Chem. Soc.</i> 85:2149-2154.
87.	Metzger, D. et al. (July 1988). "The Human Oestrogen Receptor Functions in Yeast," <i>Nature</i> 334:31-36.
88.	Miller, J. H. and Calos, M. P., eds. (1987). "Gene Transfer Vectors for Mammalian Cells," <i>In Current Communications in Molecular Biology</i> . Cold Spring Harbor Laboratory. pp. vi-ix. (Table of Contents)
89.	Morishima, H. et al. (May 1970). "The Structure of Pepstatin," <i>The J. of Antibiot.</i> 23(5):263-265.
90.	Mullis, K. B. et al. (1994). <u>The Polymerase Chain Reaction</u> . Birkhäuser, Boston, pp.xv-xvii. (Table of Contents).
91.	Murphy, G. et al., eds. (August 1991). "The N-Terminal Domain of Tissue Inhibitor of Metalloproteinases Retains Metalloproteinase Inhibitory Activity," <i>Biochemistry</i> 30(33):8097-8102.
92.	Murray, E. E. et al. (1989). "Codon Usage in Plant Genes," <i>Nucleic Acids Res.</i> 17(2):477-498.
93.	Nakajima, K. and Powers, J. C. (May 1979). "Mapping the Extended Substrate Binding Site of Cathepsin G and Human Leukocyte Elastase: Studies with Peptide Substrates Related to the $\alpha_1$ -Protease Inhibitor Reactive Site," <i>The J. of Biol. Chem.</i> 254(10):4027-4032.
94.	Otlewski, J. et al. (1999). "Protein Inhibitors of Serine Proteinases," <i>Acta Biochimica Polonica</i> 46(3):531-565.
95.	Pearson, W. R. and Lipman, D. J. (April 1988). "Improved Tools for Biological Sequence Comparison," <i>Proc. Natl. Acad. Sci.</i> 85:2444-2448.

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449  INFORMATION DISCLOSURE CITATION IN AN APPLICATION  (Use several sheets if necessary)		Docket Number 368292000200	Application Number 10/025,514
		Applicant	Philip J. BARR et al.
		Filing Date December 18, 2001	Group Art Unit 1653
		Mailing Date May <u>10</u> , 2002	<b>COPY</b>

96.	Pennington, M. W. et al. (1990). <u>Twenty-First European Peptide Symposium</u> . Gimel E. and Andrew D, eds. Escom; Leiden , Netherlands, pgs. xvii-li. (Table of Contents).
97.	Pinkert, C. A. et al. (1987). "An Albumin Enhancer Located 10 kb Upstream Functions Along with its Promoter to Direct Efficient, Liver-Specific Expression in Transgenic Mice," <i>Genes &amp; Dev.</i> 1:268-276.
98.	Potempa, J. et al. (June 1994). "The Serpin Superfamily of Proteinase Inhibitors: Structure, Function, and Regulation," <i>The J. of Biol. Chem.</i> 269(23):15957-15960.
99.	Queen, C. and Baltimore, D. (July 1983). "Immunoglobulin Gene Transcription Is Activated by Downstream Sequence Elements," <i>Cell</i> 33:741-748.
100.	Sambrook, J. et al. (1989). <u>Molecular Cloning: A Laboratory Manual</u> 2nd ed. Cold Spring Harbor Laboratory Press, Vol. 1-3., pp. xi-xxxviii. (Table of Contents).
101.	Scopes, R. K. (1982). <u>Protein Purification: Principles and Practice</u> . Springer-Verlag, N.Y. pp. xiv-xiii. (Table of Contents).
102.	Smith, D. B. and Johnson, K.S. (1988). "Single-Step Purification of Polypeptides Expressed in <i>Escherichia Coli</i> as Fusions with Glutathione S-Transferase," <i>Gene</i> 67:31-40.
103.	Stevenson-Stetler, W. G. et al. (August 1990). "Tissue Inhibitor of Metalloproteinases-2 (TIMP-2): mRNA Expression in Tumor Cell Lines and Human Tumor Tissues," <i>The J. of Biol. Chem.</i> 265(23):13933-13938.
104.	Teshima, T. et al. (May 1982). "A New Class of Heterocyclic Serine Protease Inhibitors," <i>The J. of Biol. Chem.</i> 257(9):5085-5091.
105.	Turk, V. and Bode, W. (July 1991). "The Cystatins: Protein Inhibitors of Cysteine Proteinases," <i>FEBS Lett.</i> 285(2):213-219.
106.	Umezawa, H. et al. (May 1970). "Pepstatin , A New Pepsin Inhibitor Produced By Actinomycetes," <i>The J. of Antibiot.</i> 23(5):259-262.
107.	Vogelmeier, C. et al. (1990). "Aerosolization of Recombinant SLPI to Augment Antineutrophil Elastase Protection of Pulmonary Epithelium," <i>J. Appl. Physiol.</i> 69(5):1843-1848.
108.	Wada, K. et al. (1992). "Codon Usage Tabulated from the GenBank Genetic Sequence Data," <i>Nucleic Acids Res.</i> 20:2111-2118.
109.	Weir, D. M., eds. <u>Handbook of Experimental Immunology in Four Volumes</u> . L.A. Herzenberg and C. Blackwell co-eds., Blackwell Scientific Publications, Oxford, Total pages 27. (Table of Contents for Volumes 1-4).
110.	Wilde, C. G. et al. (1994). "Cloning and Characterization of Human Tissue Inhibitor of Metalloproteinases-3," <i>DNA and Cell Biol.</i> 13(7):711-718.
111.	Wilhem, S. M. et al. (October 1987). "Human Skin Fibroblast Stromelysin: Structure, Glycosylation, Substrate Specificity, and Differential Expression in Normal and Tumorigenic Cells," <i>Proc. Natl. Acad. Sci.</i> 84:6725-6729.

EXAMINER:	DATE CONSIDERED:
EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.	

<p>Form PTO-1449 <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b> <i>(Use several sheets if necessary)</i></p>	Docket Number 368292000200	Application Number 10/025,514
	Applicant	Philip J. BARR et al.
	Filing Date December 18, 2001	Group Art Unit 1653
	Mailing Date May <u>10</u> , 2002	<b>COPY</b>

112.	Willenbrock, F. et al. (1993). "The Activity of the Tissue Inhibitors of Metalloproteinases Is Regulated by C-Terminal Domain Interactions: A Kinetic Analysis of the Inhibition of Gelatinase A," <i>Biochemistry</i> 32(16):4330-4337.
113.	Winoto, A. and Baltimore, D. (1989). "A Novel, Inducible and T Cell-Specific Enhancer Located at the 3' End of the T Cell Receptor $\alpha$ Locus," <i>The EMBO Journal</i> 8(3):729-733.
114.	Woessner, F. J., Jr. (May 1991). "Matrix Metalloproteinases and Their Inhibitors in Connective Tissue Remodeling," <i>The FASEB J.</i> 5:2145-2154 .

EXAMINER:	DATE CONSIDERED:
<p>EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.</p>	